

Amendments to the Claims:

1. (Currently amended) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN- β) or biologically active variant thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises a buffer at a concentration of about 2 mM to about 7 mM, said composition having a pH within plus or minus 0.5 units of a specified pH, where the specified pH is about 3.0 to about 5.0, said formulation having an ionic strength that is not greater than about ~~60~~20 mM, and wherein said composition further comprises trehalose; said biologically active variant of IFN- β having the ability to bind to IFN- β receptors.
2. (Original) The composition of claim 1, wherein said trehalose is present at a concentration of about 9% by weight per volume.
3. (Currently amended) The composition of claim 1, wherein said buffer is present at a concentration of about 2 mM to about 5 mM, ~~and said ionic strength is not greater than about 20 mM.~~
4. (Original) The composition of claim 1, wherein said specified pH is about 4.0 and wherein said buffer is aspartic acid.
5. (Original) The composition of claim 1, wherein said composition is a liquid.
6. (Original) The composition of claim 1, wherein said IFN- β is recombinantly produced.

7. (Original) The composition of claim 6, wherein said IFN- β is human IFN- β (hIFN- β) or biologically active mutein thereof.

8. (Original) The composition of claim 7, wherein said mutein is hIFN- β_{ser17} .

9. (Currently amended) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN- β) or biologically active variant thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises aspartic acid as a buffer, where said buffer is present at a concentration of about 1 mM to about ~~30~~20 mM, said composition having a pH of about 3.5 to about 4.5, and wherein said formulation has an ionic-strength that is not greater than about ~~60~~20 mM, wherein said composition further comprises trehalose; said biologically active variant of IFN- β having the ability to bind to IFN- β receptors.

10. (Currently amended) The composition of claim 9, wherein said buffer is present at a concentration of about 2 mM to about 5 mM; and said pH is about 4.0; ~~and said ionic-strength is not greater than about 20 mM.~~

11. (Original) The composition of claim 10, wherein said composition comprises about 9% trehalose by weight per volume.

12. (Original) The composition of claim 9, wherein said IFN- β is recombinant human IFN- β (rhIFN- β) or biologically active mutein thereof.

13. (Original) The composition of claim 12, wherein said mutein is hIFN- β_{ser17} .

14. (Original) The composition of claim 9, wherein said IFN- β or biologically active variant thereof is present at a concentration of about 0.01 mg/ml to about 20.0 mg/ml.

15. (Currently amended) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN- β) or biologically active variant thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises aspartic acid as a buffer, where said buffer is present at a concentration of about 2 mM to about 7 mM, said composition having a pH of about 3.5 to about 4.5, and wherein said formulation has an ionic-strength that is not greater than about ~~60~~20 mM, said composition further comprising trehalose; said biologically active variant of IFN- β having the ability to bind to IFN- β receptors.

16. (Currently amended) The composition of claim 15, wherein said buffer is present at a concentration of about 2 mM to about 5 mM; and said pH is about 4.0; ~~and said ionic-strength is not greater than about 20 mM.~~

17. (Original) The composition of claim 16, wherein said composition comprises about 9% trehalose by weight per volume.

18. (Original) The composition of claim 15, wherein said IFN- β is recombinant human IFN- β (rhIFN- β) or biologically active mutein thereof.

19. (Original) The composition of claim 18, wherein said mutein is hIFN- β_{ser17} .

20. (Currently amended) A method for preparing an HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN- β) or biologically active variant thereof, said method comprising preparing said composition with a low-ionic-strength formulation and trehalose, wherein said low-ionic-strength formulation is a solution that comprises aspartic acid as a buffer, where said buffer is present at a concentration of about 2 mM to about 7 mM, said composition having a pH of about 3.5 to about 4.5, and wherein said

formulation has an ionic-strength that is not greater than about ~~60~~20 mM, and incorporating IFN- β or biologically active variant thereof into said composition; said biologically active variant of IFN- β having the ability to bind to IFN- β receptors.

21. (Currently amended) The method of claim 20, wherein said buffer is present at a concentration of about 2 mM to about 5 mM; and said pH is about 4.0, ~~and said ionic strength is not greater than about 20 mM.~~

22. (Original) The method of claim 21, wherein said composition comprises about 9% trehalose by weight per volume.

23. (Original) The method of claim 20, wherein said composition is a liquid.

24. (Original) A pharmaceutical composition produced according to the method of claim 20.

25. (New) The composition of claim 1, wherein the ionic strength of said formulation is solely determined by the concentration of said buffer.

26. (New) The composition of claim 25, wherein said specified pH is about 4.0 and wherein said buffer is aspartic acid.